

CHARGE: 501 (b)—the article, while held for sale, purported to be a drug, "Digitalis Tablets," the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from, and its quality fell below, the standard set forth in that compendium.

DISPOSITION: 5-13-57. Default—destruction.

5330. Digitoxin powder. (F. D. C. No. 40111. S. No. 56-160 M.)

QUANTITY: 2 25-gram btl. at Chicago, Ill.

SHIPPED: 1-16-57, from New York, N. Y., by European Chemical Co., Inc.

LABEL IN PART: (Btl.) "Digitoxin U. S. P. * * * Assay: Digitoxin 99.10% Loss on drying 0.62%."

RESULTS OF INVESTIGATION: Examination showed that the article contained not more than 85 percent of digitoxin when assayed by the method specified in the United States Pharmacopeia. The Pharmacopeia requires that the assay result be not less than 90 percent.

LIBELED: 3-28-57, N. Dist. Ill.

CHARGE: 501 (b)—The article, when shipped, purported to be a drug, "Digitoxin," the name of which is recognized in the United States Pharmacopeia, and its strength differed from, and its quality fell below, the standard set forth in that compendium.

DISPOSITION: 4-23-57. Default—destruction.

5331. Digitoxin powder and digitoxin tablets. (F. D. C. No. 40121. S. Nos. 38-204/5 M.)

QUANTITY: 1 6-gram btl. and 1 40,000-tablet drum at St. Louis, Mo.

SHIPPED: 12-14-56, from New York, N. Y., by H. Reisman Corp.

LABEL IN PART: (Btl.) "Digitoxin U. S. P. * * * For Manufacturing, Processing or Repacking"; (drum) "0.2 mg. C. T. Digitoxin."

RESULTS OF INVESTIGATION: The above tablets were prepared by the consignee from a portion of the bulk *digitoxin powder* shipped on the above date.

Examination showed that the powder contained not more than 83.5 percent digitoxin and that the tablets contained not more than 0.156 milligram of digitoxin per tablet when assayed by the method specified in the United States Pharmacopeia. The Pharmacopeia requires that the assay results be not less than 90 percent of the labeled amount of digitoxin.

LIBELED: 4-4-57, E. Dist. Mo.

CHARGE: 501 (b)—the article, when shipped and while held for sale, purported to be a drug, "Digitoxin," the name of which is recognized in the United States Pharmacopeia, an official compendium, and its strength differed from, and its quality fell below, the standard set forth in that compendium.

DISPOSITION: 4-30-57. Default—destruction.

5332. Digitoxin tablets. (F. D. C. No. 40162. S. No. 38-211 M.)

QUANTITY: 34,772 tablets at St. Louis, Mo.

SHIPPED: 7-6-56 and 11-26-56, from New York, N. Y.

LABEL IN PART: "109a Compressed Tablets Digitoxin, 0.2 mg. Each Tablet Contains: Digitoxin, U. S. P. * * * 0.2 mg."

RESULTS OF INVESTIGATION: The tablets were prepared from bulk digitoxin powder which had been shipped to St. Louis, Mo., as described above.

Examination showed that the tablets contained not more than 0.115 milligram of digitoxin per tablet, which equaled 57.3 percent of the declared amount of digitoxin.

LIBELED: 4-11-57, E. Dist. Mo.

CHARGE: 501 (b)—while held for sale, the strength of the tablets differed from, and their quality fell below, the standard for digitoxin set forth in the United States Pharmacopeia since the article contained less than 90 percent of the labeled amount of digitoxin.

DISPOSITION: 5-10-57. Default—destruction.

5333. Del-Caps 15 capsules. (F. D. C. No. 40065. S. No. 38-293 M.)

QUANTITY: 20 1,000-capsule btls. at St. Louis, Mo.

SHIPPED: 1-25-57, from Rensselaer, N. Y., by Delmar Pharmacal Corp.

LABEL IN PART: (Btl.) "Del-Caps 15 * * * Each capsule contains: Dextro Amphetamine Sulfate 15 mg."

RESULTS OF INVESTIGATION: Examination showed that the article contained not more than 11.5 milligrams of dextro-amphetamine sulfate per capsule.

LIBELED: 3-21-57, Dist. Mo.

CHARGE: 501 (c)—the strength of the article, when shipped, differed from that which it purported and was represented to possess; and 502 (a)—the label statement "Each capsule contains: Dextro Amphetamine Sulfate 15 mg." was false and misleading.

DISPOSITION: 4-16-57. Default—destruction.

5334. Neo-Colivone. (F. D. C. No. 39754. S. No. 62-688 M.)

QUANTITY: 35 100-cc. vials at Lakewood, N. J.

SHIPPED: 10-15-56, from New York, N. Y., by Vincent Christina & Co.

RESULTS OF INVESTIGATION: Examination showed that the article contained about 70 percent of the declared amount of vitamin B₁.

LIBELED: 1-16-57, Dist. N. J.

CHARGE: 501 (c)—the strength of the article, when shipped, differed from that which it purported and was represented to possess, namely, 25 milligrams of vitamin B₁ (thiamine HCl) per cubic centimeter; and 502 (a)—the label statement "each cc. contains: Thiamine Hcl 25 mg." was false and misleading.

DISPOSITION: 2-19-57. Default—destruction.

5335. Vitamin tablets. (F. D. C. No. 40167. S. No. 59-353 M.)

QUANTITY: 10 250-tablet btls. and 347 28-tablet btls. at Philadelphia, Pa.

SHIPPED: On an unknown date, from Brooklyn, N. Y., by Sweet Laboratories.

LABEL IN PART: "Halbee-G High Potency * * * chewing (gum) tablets
Ingredients: Vitamin B₁ 10 mg. * * * Vitamin B₁₂ 25 mcg."

RESULTS OF INVESTIGATION: Examination showed that the article contained less than 5 mg. of vitamin B₁ per tablet.

LIBELED: 4-17-57, E. Dist. Pa.